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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/628,186 | 07/28/2000 | Paul Chinn | P 037003 0280721 | 2673 |

7590 05/26/2004
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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

628,186

Applicant(s)

CHINN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/5/04
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-16, 18, 49-63 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-4, 6-8, 10-13, 18, 49, 52-55, 60-63 is/are rejected.
- ☒ Claim(s) 5, 9, 14-16, 50-51, 56-59 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The amendment of 4/5/04 has been entered. Claims 1-16, 18, 49-63 are pending and under examination.

The amendment and urgings have overcome 112, first and second paragraph rejections of record. The examiner considers recitation of "at least about" in claims 52-55 to represent a rounding off from three to two significant figures.

A new basis of prior art rejection is stated supra.

Claims 1-4, 6-8, 10-13, 18, 49, 52-55 and 60-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Albert et al (5,650,134).

Albert et al show somatostatin peptides conjugated at their N-terminal, to a chelating moiety. These compounds thus fall within the scope of the instantly recited "peptide" and "ligand" (since somatostatin peptides bind to receptors; see col. 1, line 10).

Example 11 shows the limitations of instant claim 1. The radiochemical purity is 99.5% (col.19, lines 46-47); Examiner takes "radiochemical purity" to be equivalent to "radioincorporation," since applicant has argued such in the response of 4/5/04.

The examiner calculates the specific activity as approx. 800mci/mg. See attached sheet of calculations. Therein, examiner has estimated the m.w. of the chelator peptide conjugate (compound of Example 3) as approx. 2000g. The octreotide moiety is estimated to be approx. 880g (taking 110g as the av. m.w. of an amino acid residue). The examiner also guesstimates the m.w. of the linker and chelater to be approx 1000. The peptide and chelating moieties together thus add up to 1880g; and this is rounded-off to 2000g. The examiner has no time to calculate the actual m.w. by

Art Unit: 1616

adding up the atomic weights of each constituent of the compound of example 3. If examiner has over estimated the m.w. by a factor of two, then the calculated specific activity would be 1600 mci/mg. If examiner has under estimated the m.w. by a factor of two, then the calculated specific activity would be 400mci/mg. In any case, the calculated values well exceed instantly recited "5mci/mg."

Instant dependent claims 2-4 are included since example 11 shows 90 Y as the isotope. Claims 6-7 and 49 are included because Albert et al incubate for three minutes (col.19, line 43). Claim 18 is included since compound of Ex. 3 has a DTPA derivative as the chelating group. Claims 10-13 are included, since the 0.1M NH₄OAC solution at pH 5.0 (col.19, line 42) is considered to provide acceptable pH and buffering conditions. The incubation at room temperature (col.19, line 43) is consistent with "about 25 degrees C."

Claims 52-55 and 62-63 are included since all recited values are consistent with the disclosed radiochemical purity of 99.5%.

The binding specificities recited in claims 18 and 60-61 are considered consistent with the disclosure that the chelating group is attached to an amino group which does not significantly interfere with or prevent receptor binding of the thus modified peptide (col.1, lines 22-24).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is

Art Unit: 1616


571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

May 11, 2004


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644

628186

ATTACHMENT

CALCULATION OF SPECIFIC ACTIVITY OF ^{90}Y LABELED COMPOUND (5, 650, 134, EXAMPLE 11)

0.16 mCi ^{90}Y ADDED TO 11 μL OF 9 μM
CHELATING PEPTIDE (COMPOUND OF EX. 3).

ASSUME M.W. OF COMPOUND IS CA. 2000 g.

THE NO. OF MOLES OF COMPOUND PRESENT IN
11 μL OF A 9 μM SOLUTION IS:

$$\frac{11 \mu\text{L}}{10^6 \mu\text{L/L}} \times 9 \times 10^{-6} \text{ mol/L} =$$

$$\underbrace{99}_{\substack{\text{ROUND} \\ \text{OFF}}} \times \underbrace{10^{-6} \times 10^{-6}}_{10^{-12}} \text{ mol} =$$

$$10^{-10} \text{ mols OF COMPOUND}$$

TO CONVERT TO GRAMS OF WEIGHT OF COMPOUND,
ASSUMING 2000 g.m.w., ONE HAS

$$10^{-10} \text{ mol} \times 2000 \text{ g/mol} =$$

$$10^{-10} \times 2 \times 10^3 = 2 \times 10^{-7} \text{ g}$$

$$= 2 \times 10^{-4} \text{ mg}$$

SPECIFIC ACTIVITY IS THEN:

$$\frac{0.16 \text{ mCi}}{2 \times 10^{-4} \text{ mg}} = \frac{16 \times 10^{-2} \text{ mCi}}{2 \times 10^{-4} \text{ mg}} = \frac{8 \text{ mCi}}{10^{-2} \text{ mg}} = \frac{800 \text{ mCi}}{\text{mg}}$$